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PATENT COOPERATION TREATY

PCT

INTERNATIONAL-TYPE SEARCH REPORT

(PCT Article 15.5)

G9/308,435

National application No. 9801288-3	Country or Office of filing SE	Applicant's or agent's file reference H 1939-1 SE
Filing date (day/month/year) 14 April 1998		(Earliest) Priority Date (day/month/year)
Applicant Astra Aktiebolag		

Date of request for international-type search 14 April 1998	International-type search request No. SE 98/00342
--	--

This international-type search report has been prepared by this International Searching Authority and is transmitted to the applicant.

This international-type search report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (See Box I).
2. ☒ Unity of invention is lacking (See Box II).
3. ☐ The international application contains disclosure of a nucleotide and/or amino acid sequence listing and the international-type search was carried out on the basis of the sequence listing

☐ filed with the international application.
☐ furnished by the applicant separately from the international application,

☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.

☐ transcribed by this Authority.

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Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international-type search report has not been established in respect of certain claims for the following reasons:

1. ☐ Claims No.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims No.:
because they relate to parts of the national application that do not comply with the prescribed requirements to such an extent that no meaningful international-type search can be carried out, specifically:

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this application, as follows:

see next sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international-type search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international-type search report covers only those claims for which fees were paid, specifically claims No.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international-type search report is restricted to the invention first mentioned in the claims, it is covered by claims No.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

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The following two inventions have been found:

Claims 1-37: A method of producing polymer particles with incorporated antigens - which have been made water soluble with the aid of e.g. a detergent - in which an aqueous phase (W) with the solubilised antigens and a stabilising additive is mixed with an "organic phase" (O) containing a matrix-forming polymer producing a W/O emulsion. Forming droplets of the W/O emulsion in a "fluid medium" in the presence of said solubilising component (e.g. detergent) such that the solvent used in the O phase can be driven off, thereby producing polymer particles incorporating said protein antigens.

Claims 38-52: Production of a "polymer particle vaccine delivery system" in which water insoluble protein antigens are incorporated in a polymer matrix, particularly *Helicobacter pylori* antigens.

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A. CLASSIFICATION OF SUBJECT MATTER		
IPC6: A61K 39/39, A61K 9/16 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
IPC6: A61K		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
SE,DK,FI,NO classes as above		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 9511009 A1 (GENENTECH, INC.), 27 April 1995 (27.04.95), see page 3, lines 19-23, page 4-5 and page 7, lines 13-18 --	1-37
X	WO 9511010 A1 (GENENTECH, INC.), 27 April 1995 (27.04.95), see table 12 --	1-37
X	WO 9636317 A1 (ALKERMES CONTROLLED THERAPEUTICS, INC.), 21 November 1996 (21.11.96), see page 22, lines 3-17, page 20, lines 8-20, 30-31 --	1-37
X	US 5075109 A (THOMAS R. TICE ET AL), 24 December 1991 (24.12.91), see column 18-20 --	1-37
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.		
* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international-type search		Date of mailing of the international-type search report
3 December 1998		1999 -01- 13
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86		Authorized officer Carl-Olof Gustafsson Telephone No. +46 8 782 25 00

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5622649 A (ROBERT L. HUNTER ET AL), 22 April 1997 (22.04.97), see examples 15 and 16 and figures 9 and 10 --	1-37
A	Chemical Abstracts, Volume 124, No 6, 5 February 1996 (05.02.96), (Columbus, Ohio, USA), Greenway, Terrence E. et al, "Enhancement of protective immune responses to Venezuelan equine encephalitis (VEE) virus with microencapsulated vaccine", page 1, THE ABSTRACT No 66330, Vaccine 1995, 13 (15), 1411-1420 --	1-37
A	EP 0766967 A1 (MALLINCKRODT VETERINARY LIMITED), 9 April 1997 (09.04.97) --	1-37
P,X	WO 9828357 A1 (CONNAUGHT LABORATORIES LIMITED), 2 July 1998 (02.07.98), see examples 20-21, figure 20 and pages 11 and 20 --	1
A	US 5417986 A (ROBERT H. REID ET AL), 23 May 1995 (23.05.95) --	1-37
A	Research in immunology, Volume 149, 1998, J.L. Cleland, "Development of stable formulations for PLGA/PLA microsphere vaccines" page 45 - page 47 --	1-37
AX	Dev Biol Stand, Volume 92, 1998, R.K. Gupta et al, "Biodegradable Polymer Microspheres as Vaccine Adjuvants and Delivery Systems" page 63 - page 78 --	1-37

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SE 98/00342

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	Advanced Drug Delivery Reviews, Volume 32, 1998, Derek T. O'hagan et al, "Poly(lactide-co-glycolide) microparticles for the development of single-dose controlled-release vaccines" page 225 - page 246 --	1-37
X	US 4919929 A (LEE R. BECK), 24 April 1990 (24.04.90), see column 3-6, example 2 and claims	38,50
Y	--	39-41,45-49
X	US 5529777 A (ALEXANDER K. ANDRIANOV ET AL), 25 June 1996 (25.06.96), see column 3-4, examples 3 and 7 and claims 1, 2, 8 and 9	38,50
Y	--	39-41,45-49
Y	Dialog Information Services, File Medline, Dialog accession no. 07045834, Medline accession no. 92210497, Doig P et al: "Production of a conserved adhesin by the human gastroduodenal pathogen Helicobacter pylori"; & J Bacteriol (UNITED STATES) Apr 1992, 174 (8) p2539-47 --	39-41,45-49
Y	US 5538729 A (STEVEN J. CZINN ET AL), 23 July 1996 (23.07.96) --	39-41,45-49
A	US 5591433 A (J. GABRIEL MAICHAEL ET AL), 7 January 1997 (07.01.97), see column 3 -- -----	39-41,45-49

INTERNATIONAL-TYPE SEARCH REPORT

Information on patent family members

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WO	9511009	A1	27/04/95	AU	8017494 A	08/05/95
				CA	2172508 A	27/04/95
				EP	0724433 A	07/08/96
				JP	9504026 T	22/04/97

WO	9511010	A1	27/04/95	AU	7980794 A	08/05/95
				CA	2172509 A	27/04/95
				EP	0724432 A	07/08/96
				JP	9504027 T	22/04/97

WO	9636317	A1	21/11/96	AU	5859296 A	29/11/96
				CA	2221496 A	21/11/96
				CN	1184420 A	10/06/98
				CZ	9703582 A	17/06/98
				EP	0827396 A	11/03/98
				NO	975269 A	15/01/98
				PL	323382 A	30/03/98

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US	5075109	A	24/12/91	AT	140386	T	15/08/96
				AU	633483	B	04/02/93
				AU	3343389	A	05/10/89
				CN	1043442	A	04/07/90
				DE	68926828	D,T	09/01/97
				DK	222490	A	16/11/90
				EP	0333523	A,B	20/09/89
				SE	0333523	T3	
				EP	0706792	A	17/04/96
				ES	2088890	T	01/10/96
				GR	3020569	T	31/10/96
				HK	38897	A	04/04/97
				IN	169330	A	28/09/91
				JP	2521827	B	07/08/96
				JP	3503892	T	29/08/91
				NZ	241319	A	22/09/97
				US	5811128	A	22/09/98
				US	5814344	A	29/09/98
				US	5820883	A	13/10/98
				WO	8908449	A	21/09/89
				AT	108650	T	15/08/94
				AU	607439	B	07/03/91
				AU	7992987	A	28/04/88
				CA	1331738	A	30/08/94
				CN	1036326	A	18/10/89
				DE	3750247	D,T	27/10/94
				DK	557787	A	25/04/88
				EP	0266119	A,B	04/05/88
				SE	0266119	T3	
				ES	2056068	T	01/10/94
				HK	122495	A	04/08/95
				IE	64786	B	06/09/95
				IN	170283	A	07/03/92
				JP	2741728	B	22/04/98
				JP	63190833	A	08/08/88
				SG	168394	A,G	16/06/95
				ZA	8707946	A	26/04/88

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Information on patent family members

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US	5622649	A	22/04/97	AT	165749	T	15/05/98
				AU	2316892	A	25/01/93
				CA	2112356	A	07/01/93
				CN	1073889	A	07/07/93
				CN	1096224	A	14/12/94
				DE	69225404	D	00/00/00
				EP	0591452	A,B	13/04/94
				SE	0591452	T3	
				ES	2116340	T	16/07/98
				IE	67066	B	21/02/96
				IL	107262	D	00/00/00
				JP	6508555	T	29/09/94
				WO	9300160	A	07/01/93

EP	0766967	A1	09/04/97	AU	637405	B	27/05/93
				AU	6335590	A	08/04/91
				CA	2064911	A	02/03/91
				DD	297331	A	09/01/92
				EP	0415794	A	06/03/91
				HR	930517	A	31/08/97
				HU	214110	B	29/12/97
				JP	5500056	T	14/01/93
				LV	10394	A,B	20/02/95
				PL	168055	B	30/12/95
				PL	168316	B	29/02/96
				PT	95164	A,B	22/05/91
				US	5178860	A	12/01/93
				WO	9103256	A	21/03/91

WO	9828357	A1	02/07/98	AU	5472198	A	17/07/98

US	5417986	A	23/05/95	US	5693343	A	02/12/97
				US	5762965	A	09/06/98
				AU	8303691	A	21/12/92
				WO	9219263	A	12/11/92
				AU	7558991	A	10/10/91
				US	5470311	A	28/11/95
				WO	9113595	A	19/09/91

US	4919929	A	24/04/90	US	4956349	A	11/09/90
				US	5242691	A	07/09/93
				US	5352462	A	04/10/94
				US	5650175	A	22/07/97

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01/12/98

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US	5529777	A	25/06/96	AU	690567	B	30/04/98
				AU	7328694	A	13/02/95
				BR	9407397	A	05/11/96
				CA	2167081	A	26/01/95
				CN	1128953	A	14/08/96
				EP	0792161	A	03/09/97
				JP	9500132	T	07/01/97
				WO	9502416	A	26/01/95
				AU	691824	B	28/05/98
				AU	7326194	A	13/02/95
				BR	9407051	A	13/08/96
				CA	2166208	A	26/01/95
				CN	1128954	A	14/08/96
				EP	0710117	A	08/05/96
				JP	9500629	T	21/01/97
				SG	46659	A	20/02/98
				US	5494673	A	27/02/96
				US	5562909	A	08/10/96
				WO	9502415	A	26/01/95
				WO	9502628	A	26/01/95

US	5538729	A	23/07/96	AU	675938	B	27/02/97
				AU	3977093	A	18/11/93
				BG	98294	A	28/02/95
				BR	9305482	A	04/10/94
				CA	2111189	A	28/10/93
				CZ	9302730	A	13/04/94
				EP	0590138	A	06/04/94
				FI	935591	A	11/02/94
				HU	67058	A	30/01/95
				HU	214699	B	28/04/98
				HU	9303561	D	00/00/00
				JP	7500845	T	26/01/95
				MX	9301706	A	31/05/94
				NO	934547	A	10/02/94
				NZ	251849	A	24/06/97
				SK	141293	A	06/07/94
				WO	9320843	A	28/10/93

INTERNATIONAL-TYPE SEARCH REPORT

Information on patent family members

01/12/98

Search request No.

SE 98/00342

US	5591433	A	07/01/97	WO	9628413	A	19/09/96
				AT	143803	T	15/10/96
				AU	664222	B	09/11/95
				AU	3104593	A	07/07/94
				CA	2086631	A	23/06/94
				DE	69305313	D,T	20/02/97
				DK	603992	T	24/03/97
				EP	0603992	A,B	29/06/94
				SE	0603992	T3	
				ES	2095001	T	01/02/97
				GR	3022090	T	31/03/97
				JP	7010771	A	13/01/95
				NZ	245618	A	26/10/94
				US	5609871	A	11/03/97
				US	5629001	A	13/05/97
				US	5783193	A	21/07/98
				AT	158180	T	15/10/97
				AU	664561	B	23/11/95
				AU	2249692	A	25/01/93
				CA	2110899	A	07/01/93
				DE	69222306	D,T	09/04/98
				DK	590060	T	11/05/98
				EP	0590060	A,B	06/04/94
				SE	0590060	T3	
				ES	2109362	T	16/01/98
				GR	3025628	T	31/03/98
				JP	6508371	T	22/09/94
				WO	9300077	A	07/01/93

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